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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,268	03/19/2002	Christian Kropf	H 4086 PCT/US	9035

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EXAMINER	
GRAFFEO, MICHELLE	

ART UNIT	PAPER NUMBER
1614	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/030,268	KROPF ET AL.	
	Examiner	Art Unit	
	Michelle Graffeo	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 May 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16-21,28,31 and 32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16-21,28,31 and 32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Action

Claims 16-21, 28 and 31-32 are pending and examined.

In response to the Office Action dated May 4, 2005, Applicant has filed a certified copy of the priority document, DE 199 30 335.5 as required by 35 U.S.D. 119(b), amended claims 16-17, cancelled claims 22 and 30 and added claims 31 and 32.

Receipt is acknowledged of the priority document, DE 199 30 335.5 submitted under 35 U.S.C. 119(a)-(d), which has been placed of record in the file.

Applicant's arguments, see Amendment, filed May 4, 2005, with respect to claims 16-17 and 30 have been fully considered and are persuasive. The objection of claims 16-17 and 30 has been withdrawn.

Applicant's request that the provisional Double Patenting rejection be held in abeyance until it is made permanent is noted but will be maintained in this Office Action and future Office Actions until withdrawn.

Any rejection not specifically stated in this Office Action has been withdrawn.

Maintained Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 16-21, 28 and 31-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over PCT/IB97/01634 to Rudin *et al.* in view of United States Patent No. 4,853,225 to Wahlig *et al.*, and further in view of Flautre et al. Journal of Materials Science: Materials In Medicine, Evaluation of Hydroxyapatite Powder Coated with Collagen as an Injectable bone Substitute: Microscopic Study in Rabbit, 7, pgs 63-67 (1996).

Rudin *et al.* teach a hydroxyapatite composite comprising finely divided rod like particles of hydroxyapatite having dimensions of 60nm (L) by 15nm (W) by 5nm (T) (see page 2 paragraph 5) and a surfactant (see page 4 paragraph 4 and Example 5 which includes polyethylene glycol) which can be used to prepare toothpastes (see Abstract).

Rudin *et al.* do not teach the incorporation of a protein, protein hydrolyzate or protein hydrolyzate derivative into the composite.

Wahlig *et al.* teach a hydroxyapatite composition which comprises collagen or from 1-20% of a collagen degradation product (see col 4 lines 62-67) which includes gelatin (see page 7 lines 24-26 and of instant specification and page 252 of Handbook of Pharmaceutical Excipients 4th Edition: Raymond C Rowe; Pharmaceutical Press, Grayslake, IL 2003 which is cited only to show the source of gelatine) for use as a dental implant which can be used as an excipient for chemotherapy agents.

It would be obvious to one skilled in the art to combine the products of Rudin *et al.* and Wahlig *et al.* since both are directed to stomatological uses. Hydroxyapatite and collagen microspheric compositions have been used as bone substitutes in Flautre et al. Journal of Materials Science: Materials In Medicine, Evaluation of Hydroxyapatite Powder Coated with Collagen as an Injectable bone Substitute: Microscopic Study in Rabbit, 7, pgs 63-67 (1996) where it was suggested that a collagen gel may improve the dispersion of hydroxyapatite granules (see page 63 first paragraph). Therefore, it would be obvious to one skilled in the art to combine the rod like shaped hydroxyapaptite particles of Rudin *et al.* with the bio-absorbable collagen and/or gelatine comprising product (see col 5 lines 14-18) excipient of Wahlig *et al.* Thus, the claimed invention of

the composition was within the ordinary skill in the art to make and use at the time it was made and was as a whole, *prima facie* obvious.

New Claim Rejections In Response to Amendment - 35 USC § 103

Claims 16-21, 28 and 31-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over PCT/IB97/01634 to Rudin *et al.* as applied to claims16-21, 28 and 31-32 above, in view of Wang et al. Synthesis of phase hydroxyapatite/collagen composit. Journal of Materials Science Letters 14 (1995) 490-492.

Wang et al. teach that nanometer sized hydroxyapatite deposits in an orderly way on a collagen matrix in natural bone (see 1st paragraph, page 490) and reports a new composite in which nanometer sized hydroxyapatite is homogeneously dispersed in a collagen matrix (see end of 1st paragraph, page 490) such that the crystal size of the hydroxyapatite is 2-10nm (see page 492).

One of ordinary skill in the art would have been motivated to combine Rudin et al. with Wang et al. and as combined teach and make obvious the invention as claimed. One of ordinary skill in the art would have been motivated to combine Rudin et al. with Wang et al. because both are directed to the use of nanoparticulate hydroxyapatite. Rudin et al. simply teach all three dimensions of the nanoparticulate hydroxyapatite while Wang et al. teach the nanoparticulate hydroxyapatite of the size in Rudin et al. dispersed in a collagen matrix. Thus, the claimed invention was within the ordinary skill in the art to make and use at the time it was made and was as a whole, *prima facie* obvious.

Maintained Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 16-22, 28 and 30 are provisionally rejected under the judicially created doctrine of double patenting over claims 8-10 and 13 of copending Application No. 09/868,379. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows in the table of comparison below:

Table of comparison between claims 16-22, 28 of the instant application and claims 8-10 and 13 of copending Application No. 09/868,379.

Claim Number (10/030268)	Claim limitations from '268	Limitations claimed in 09/868379 reference
16	A phosphate, fluoride or fluorophosphate calcium salt in form of 10-300nm diameter rod-like particles and a protein or protein derivatives.	Claim 8: A phosphate, fluoride or fluorophosphate calcium salt in form of 10-50nm diameter particles and a water-soluble polymeric protective colloid adsorbed onto said particle which can be for example casein or gelatine. See also Claims 9, 10 and 13.
17	A phosphate, fluoride or fluorophosphate calcium salt in form of rod-like particles having a thickness of 2-50nm and a length of 10-150nm and a protein or protein derivatives. Since the particle is rod-like, it would be obvious to one skilled in the art that thickness is equal to diameter.	Claim 8: A phosphate, fluoride or fluorophosphate calcium salt in form of particles having a diameter of 10-50nm and length of 10 to 150nms and a water-soluble polymeric protective colloid adsorbed onto said particle which can be for example casein or gelatine. See also Claims 9, 10 and 13.
18	A calcium salt in form of 10-300nm diameter rod-like particles and a substance selected from collagen, gelatine, keratin casein etc.	Claim 8: A phosphate, fluoride or fluorophosphate calcium salt in form of particles having a diameter of 10-50nm and a water-soluble polymeric protective colloid adsorbed onto said particle which can be for example casein or gelatine. See also Claims 9, 10 and 13.
19	A phosphate, fluoride or fluorophosphate calcium salt in form of 10-300nm diameter rod-like particles and a substance selected from gelatine, keratin casein etc.	Claim 8: A calcium salt in form of rod-like particles having a diameter of 10-50nm and a water-soluble polymeric protective colloid adsorbed onto said particle which can be for example casein or gelatine. See also Claims 9, 10 and 13.
20	A calcium salt in form of 10-300nm diameter rod-like particles and a protein or protein derivatives wherein the salt is encapsulated with one or more surface modifiers.	Claim 8: A phosphate, fluoride or fluorophosphate calcium salt in form of particles having a diameter of 10-50nm and a water-soluble polymeric protective colloid adsorbed onto said particle. See also Claims 9, 10 and 13.
21	Hydroxylapatite or fluorapatite in form of 10-300nm diameter rod-like particles and a protein or protein derivatives.	Claim 8: A phosphate, fluoride or fluorophosphate calcium salt in form of particles having a diameter of 10-50nm and a water-soluble polymeric protective colloid adsorbed onto said particle, which

		can be a protein for example casein or gelatine. See also Claims 9, 10 and 13.
22	A phosphate, fluoride or fluorophosphate calcium salt in form of 10-300nm diameter rod-like particles and a protein or protein derivatives wherein the protein or its derivative comprise 0.1 to 60% of the composite material.	Claim 8: A phosphate, fluoride or fluorophosphate calcium salt in form of particles having a diameter of 10-50nm and a water-soluble polymeric protective colloid adsorbed onto said particle, which is present in an amount of at least 0.1% of the weight of the suspension. See also Claims 9, 10 and 13 to the extent that the amount of colloid is equal to the amount of protein or protein derivative in Claim 22 of the instant application.
28	A toothpaste comprising a phosphate, fluoride or fluorophosphate calcium salt in form of 10-300nm diameter rod-like particles and a protein or protein derivatives.	Claim 13: A toothpaste comprising a one or more calcium phosphate, hydroxylapatite, flourapatite or calcium fluoride wherein the salt particles have diameters from 5-50 nm and a water-soluble polymeric protective colloid adsorbed onto said particle wherein such colloid can be a protein such as casein or gelatine.
30	A phosphate, fluoride or fluorophosphate calcium salt in form of 10-300nm diameter rod-like particles and a protein or protein derivatives wherein the protein or its derivative comprise 0.5 to 10% of the composite material.	Claim 8: A phosphate, fluoride or fluorophosphate calcium salt in form of particles having a diameter of 10-50nm and a water-soluble polymeric protective colloid adsorbed onto said particle, which is present in an amount of at least 0.1% of the weight of the suspension. See also Claims 9, 10 and 13 to the extent that the amount of colloid is equal to the amount of protein or protein derivative in Claim 22 of the instant application.

Claims 16-22, 28 and 30 are provisionally rejected under the judicially created doctrine of double patenting over claims 1-8 of copending Application No. 10/465157.

This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows in the table of comparison below:

Table of comparison between claims 16-22, 28 of the instant application and claims 1-8 of copending Application No. 10/465157.

Claim Number (10/030268)	Claim limitations from '268	Limitations claimed in 10/465157 reference
16	A phosphate, fluoride or fluorophosphate calcium salt in form of 10-300nm diameter rod-like particles and a protein or protein derivatives.	Claim 4: A phosphate, fluoride or fluorophosphate calcium salt having a mean particle fineness of 10-300nm and a water-soluble or swellable support material which can be for example casein or gelatine. See also Claims 1-3 and 5-8 to the extent that the salt particles are finely divided and finely divided can to one skilled in the art include those particles with a 10-300nm fineness. Further the specification of this reference states on page 5 that "Those only slightly water-soluble calcium salts have proven particularly advantageous which have a mean particle fineness of 10-300 nm (nanometers)."
17	A phosphate, fluoride or fluorophosphate calcium salt in form of rod-like particles having a thickness of 2-50nm and a length of 10-150nm and a protein or	Claim 4: A phosphate, fluoride or fluorophosphate calcium salt having a mean particle fineness of 10-300nm and a water-soluble or swellable support material which can be for example casein or gelatine. Claim 5: A finely divided phosphate, fluoride or

	protein derivatives.	fluorophosphate calcium salt and a protein which can be for example casein or gelatine. See also Claims 1-3 and 6-8.
18	A phosphate, fluoride or fluorophosphate calcium salt in form of 10-300nm diameter rod-like particles and a substance selected from collagen, gelatine, keratin casein etc.	Claim 4: A phosphate, fluoride or fluorophosphate calcium salt having a mean particle fineness of 10-300nm and a water-soluble or swellable support material which can be for example casein or gelatine. Claim 5: A finely divided phosphate, fluoride or fluorophosphate calcium salt and a protein which can be for example casein or gelatine. See also Claims 6-8.
19	A phosphate, fluoride or fluorophosphate calcium salt in form of 10-300nm diameter rod-like particles and a substance selected from gelatine, keratin casein etc.	Claim 4: A phosphate, fluoride or fluorophosphate calcium salt having a mean particle fineness of 10-300nm and a water-soluble or swellable support material which can be for example casein or gelatine. Claim 5: A finely divided phosphate, fluoride or fluorophosphate calcium salt and a protein which can be for example casein or gelatine. See also Claims 6-8.
20	A calcium salt in form of 10-300nm diameter rod-like particles and a protein or protein derivatives wherein the salt is encapsulated with one or more surface modifiers.	Claim 4: A phosphate, fluoride or fluorophosphate calcium salt having a mean particle fineness of 10-300nm and a water-soluble or swellable support material which can be for example casein or gelatine. Claim 5: A finely divided phosphate, fluoride or fluorophosphate calcium salt and a protein which can be for example casein or gelatine. See also Claims 1-3 and 6-8. This application does not claim surface modifiers, but surface modifiers can be emulsifiers, colloids and surfactants all of which are traditionally used in dental materials and excipients (See *Kirk-Othmer Encyclopedia of Chemical Technology* Copyright © 1993 by John Wiley & Sons, Inc. All rights reserved. DOI: 10.1002/0471238961.0405142016010405.a001 Article Online Posting Date: December 4, 2000.)
21	Hydroxylapatite or fluorapatite in form of 10-300nm diameter rod-like particles and a protein or	Claim 5: A finely divided phosphate, fluoride or fluorophosphate calcium salt and a protein which can be for example casein or gelatine. See also Claims 1-4 and 6-8.

	protein derivatives.	
22	A phosphate, fluoride or fluorophosphate calcium salt in form of 10-300nm diameter rod-like particles and a protein or protein derivatives wherein the protein or its derivative comprise 0.1 to 60% of the composite material.	Claim 8: A finely divided phosphate, fluoride or fluorophosphate calcium salt and a protein which can be for example casein or gelatine and further wherein the protein is present in an amount of 0.1 to 60%. See also Claims 1-7.
28	A toothpaste comprising a phosphate, fluoride or fluorophosphate calcium salt in form of 10-300nm diameter rod-like particles and a protein or protein derivatives.	Claim 4: A phosphate, fluoride or fluorophosphate calcium salt having a mean particle fineness of 10-300nm and a water-soluble or swellable support material which can be for example casein or gelatine. See also Claims 1-3 and 5-8. This reference does not recite a toothpaste in any claim preamble but instead recites a dental adhesive for local remineralizing tooth treatment. It would be obvious to one skilled in the art to use the reference as a toothpaste since, as the applicant admits in its specification on page 1, "Phosphate salts of calcium have long been added to the formulations of tooth cleaning and dental care preparations both as abrasive components and for promoting the remineralizing of dental enamel." Thus it would be obvious to use the dental adhesive as a toothpaste and the dental adhesive is an obvious variation on a toothpaste.
30	A phosphate, fluoride or fluorophosphate calcium salt in form of 10-300nm diameter rod-like particles and a protein or protein derivatives wherein the protein or its derivative comprise 0.5 to 10% of the composite material.	Claim 8: A finely divided phosphate, fluoride or fluorophosphate calcium salt and a protein which can be for example casein or gelatine and further wherein the protein is present in an amount of 0.1 to 60%. See also Claims 1-7.

Claims 16-22, 28 and 30 are provisionally rejected under the judicially created doctrine of double patenting over claims 20-27 of copending Application No.

10/297,889. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows in the table of comparison below:

Table of comparison between claims 16-22, 28 of the instant application and claims 20-27 of copending Application No. 10/297,889.

Claim Number (10/030268)	Claim limitations from '268	Limitations claimed in 10/297,889 reference
16	A phosphate, fluoride or fluorophosphate calcium salt in form of 10-300nm diameter rod-like particles and a protein or protein derivatives.	Claim 20: A phosphate, fluoride or fluorophosphate calcium salt having an average particle diameter of from 5-300nm and a polyelectrolyte which can be a protein (see Dictionary in AccessScience@McGraw-Hill). See also claims 21-27.
17	A phosphate, fluoride or fluorophosphate calcium salt in form of rod-like particles having a thickness of 2-50nm and a length of 10-150nm and a protein or protein derivatives.	Claim 20: A phosphate, fluoride or fluorophosphate calcium salt having an average particle diameter of from 5-300nm and a polyelectrolyte which can be a protein (see Dictionary in AccessScience@McGraw-Hill). See also claims 21-27.
18	A phosphate, fluoride or fluorophosphate calcium salt in form of 10-300nm diameter rod-like particles and a substance selected	Claim 20: A phosphate, fluoride or fluorophosphate calcium salt having an average particle diameter of from 5-300nm and a polyelectrolyte which can be a protein (see Dictionary in AccessScience@McGraw-Hill).

	from collagen, gelatine, keratin casein etc.	See also claims 21, 23-27.
19	A phosphate, fluoride or fluorophosphate calcium salt in form of 10-300nm diameter rod-like particles and a substance selected from gelatine, keratin casein etc.	Claim 20: A phosphate, fluoride or fluorophosphate calcium salt having an average particle diameter of from 5-300nm and a polyelectrolyte which can be a protein (see Dictionary in AccessScience@McGraw-Hill). See also claims 21, 23-27.
20	A calcium salt in form of 10-300nm diameter rod-like particles and a protein or protein derivatives wherein the salt is encapsulated with one or more surface modifiers.	Claim 20: A phosphate, fluoride or fluorophosphate calcium salt having an average particle diameter of from 5-300nm and a polyelectrolyte which can be a protein (see Dictionary in AccessScience@McGraw-Hill). See also claims 21-27. This application does not claim surface modifiers, but surface modifiers can be emulsifiers, colloids and surfactants all of which are traditionally used in dental materials and excipients (See *Kirk-Othmer Encyclopedia of Chemical Technology* Copyright © 1993 by John Wiley & Sons, Inc. All rights reserved. DOI: 10.1002/0471238961.0405142016010405.a001 Article Online Posting Date: December 4, 2000.)
21	Hydroxylapatite or fluorapatite in form of 10-300nm diameter rod-like particles and a protein or protein derivatives.	Claim 21: Hydroxyapatite and fluoroapatite having an average particle diameter of from 5-300nm and a polyelectrolyte which can be a protein (see Dictionary in AccessScience@McGraw-Hill). See also claims 20, 22-27.
22	A phosphate, fluoride or fluorophosphate calcium salt in form of 10-300nm diameter rod-like particles and a protein or protein derivatives wherein the protein or its derivative comprise 0.1 to 60% of the composite material.	Claim 24: A phosphate, fluoride or fluorophosphate calcium salt having an average particle diameter of from 5-300nm and a polyelectrolyte which can be a protein (see Dictionary in AccessScience@McGraw-Hill) wherein the polyelectrolyte/protein is 0.1 to 40%. Claim 25: A phosphate, fluoride or fluorophosphate calcium salt having an average particle diameter of from 5-300nm and a polyelectrolyte which can be a protein (see Dictionary in AccessScience@McGraw-Hill) wherein the polyelectrolyte/protein is 2 to 50%.

		See also claims 22-23 and 26-27.
28	A toothpaste comprising a phosphate, fluoride or fluorophosphate calcium salt in form of 10-300nm diameter rod-like particles and a protein or protein derivatives.	Claim 20: A composition for treating tooth and/or bone, of which includes toothpaste, comprising a phosphate, fluoride or fluorophosphate calcium salt having an average particle diameter of from 5-300nm and a polyelectrolyte which can be a protein (see Dictionary in AccessScience@McGraw-Hill). Claim 27: A paste comprising a phosphate, fluoride or fluorophosphate calcium salt having an average particle diameter of from 5-300nm and a polyelectrolyte which can be a protein (see Dictionary in AccessScience@McGraw-Hill). See also claims 21-26.
30	A phosphate, fluoride or fluorophosphate calcium salt in form of 10-300nm diameter rod-like particles and a protein or protein derivatives wherein the protein or its derivative comprise 0.5 to 10% of the composite material.	Claim 24: A phosphate, fluoride or fluorophosphate calcium salt having an average particle diameter of from 5-300nm and a polyelectrolyte which can be a protein (see Dictionary in AccessScience@McGraw-Hill) wherein the polyelectrolyte/protein is 0.1 to 40%. Claim 25: A phosphate, fluoride or fluorophosphate calcium salt having an average particle diameter of from 5-300nm and a polyelectrolyte which can be a protein (see Dictionary in AccessScience@McGraw-Hill) wherein the polyelectrolyte/protein is 2 to 50%. See also claims 22-23 and 26-27.

Claims 16-22, 28 and 30 are provisionally rejected under the judicially created doctrine of double patenting over claims 20-27 of copending Application No. 10/297,842. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows in the table of comparison below:

Table of comparison between claims 16-22, 28 of the instant application and claims 20-27 of copending Application No. 10/297,842.

Claim Number (10/030268)	Claim limitations from '268	Limitations claimed in 10/297,842 reference
16	A phosphate, fluoride or fluorophosphate calcium salt in form of 10-300nm diameter rod-like particles and a protein or protein derivatives.	Claim 21: An oral or dental care composition comprising nanoparticulate particles hydroxides, carbonates and phosphates for example, and a surface modifying agent which includes a protein such as casein or gelatine. This claim does not recite the specific particle size, but on page 4 of the specification, a diameter range from 1-200nm is supported.
17	A phosphate, fluoride or fluorophosphate calcium salt in form of rod-like particles having a thickness of 2-50nm and a length of 10-150nm and a protein or protein derivatives.	Claim 21: An oral or dental care composition comprising nanoparticulate particles hydroxides, carbonates and phosphates for example, and a surface modifying agent which includes a protein such as casein or gelatine. This claim does not recite the specific particle size, but on page 4 of the specification, a diameter range from 1-200nm is supported. The diameter is a function of the shape of the particle of for example hydroxyapatite which crystallizes into hexagonal rhombic prisms i.e. rod-like and thus a diameter of 1-200nm would correspond to a length within the range of 10-150nm (See S. Zhang and K.E. Gonsalves, J. Mater. Sci. Mater, Med. 8 (1997) 25.)
18	A phosphate, fluoride or	Claim 21: An oral or dental care composition

	fluorophosphate calcium salt in form of 10-300nm diameter rod-like particles and a substance selected from collagen, gelatine, keratin casein etc.	comprising nanoparticulate particles hydroxides, carbonates and phosphates for example, and a surface modifying agent which includes a protein such as casein or gelatine. This claim does not recite the specific particle size, but on page 4 of the specification, a diameter range from 1-200nm is supported.
19	A phosphate, fluoride or fluorophosphate calcium salt in form of 10-300nm diameter rod-like particles and a substance selected from gelatine, keratin casein etc.	Claim 21: An oral or dental care composition comprising nanoparticulate particles hydroxides, carbonates and phosphates for example, and a surface modifying agent which includes a protein such as casein or gelatine. This claim does not recite the specific particle size, but on page 4 of the specification, a diameter range from 1-200nm is supported.
20	A calcium salt in form of 10-300nm diameter rod-like particles and a protein or protein derivatives wherein the salt is encapsulated with one or more surface modifiers.	Claim 21: An oral or dental care composition comprising nanoparticulate particles hydroxides, carbonates and phosphates for example, and a surface modifying agent which includes a protein such as casein or gelatine. This claim does not recite the specific particle size, but on page 4 of the specification, a diameter range from 1-200nm is supported.
21	Hydroxylapatite or fluorapatite in form of 10-300nm diameter rod-like particles and a protein or protein derivatives.	Claim 21: An oral or dental care composition comprising nanoparticulate particles hydroxides, carbonates and phosphates which include for example, hydroxylapatite and fluorapatite, and a surface modifying agent which includes a protein such as casein or gelatine. This claim does not recite the specific particle size, but on page 4 of the specification, a diameter range from 1-200nm is supported.
22	A phosphate, fluoride or fluorophosphate calcium salt in form of 10-300nm diameter rod-like particles and a protein or protein derivatives wherein the protein or its derivative comprise 0.1 to 60% of the composite material.	Claim 21: An oral or dental care composition comprising nanoparticulate particles hydroxides, carbonates and phosphates for example, and a surface modifying agent which includes a protein such as casein or gelatine to the extent that the protein is present in an amount from 0.1 to 60%. This claim does not recite the specific particle size, but on page 4 of the specification, a diameter range from 1-200nm is supported.
28	A toothpaste comprising a phosphate, fluoride or fluorophosphate calcium salt	Claim 21: An oral or dental care composition, of which a toothpaste is, comprising nanoparticulate particles hydroxides, carbonates

	in form of 10-300nm diameter rod-like particles and a protein or protein derivatives.	and phosphates for example, and a surface modifying agent which includes a protein such as casein or gelatine. This claim does not recite the specific particle size, but on page 4 of the specification, a diameter range from 1-200nm is supported.
30	A phosphate, fluoride or fluorophosphate calcium salt in form of 10-300nm diameter rod-like particles and a protein or protein derivatives wherein the protein or its derivative comprise 0.5 to 10% of the composite material.	Claim 21: An oral or dental care composition comprising nanoparticulate particles hydroxides, carbonates and phosphates for example, and a surface modifying agent which includes a protein such as casein or gelatine to the extent that the protein is present in an amount from 0.5 to 10%. This claim does not recite the specific particle size, but on page 4 of the specification, a diameter range from 1-200nm is supported.

Response to Amendment

The amendment filed August 8, 2005 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the phrase "wherein the rodlet-like primary nanoparticles of the calcium salts are uniformly associated onto the skeleton of the protein component." in claim 16 is not supported by the original specification. In particular, Example 2 discloses the production of a composite of hydroxylapatite and gelatine made by incorporating dispersions of calcium salts in protein components. The specification is therefore lacking support for a composite material wherein the calcium salts are uniformly associated onto a protein skeleton.

Applicant is required to cancel the new matter in the reply to this Office Action.

Response to Arguments

Applicant's arguments filed August 8, 2005 have been fully considered but they are not persuasive. The Examiner maintains that Rudin et al. teach rodlet like hydroxylapatite particles having dimensions of 60nm (L) by 15nm (W) by 5nm (T) (see page 2 paragraph 5). The reference supplied by Applicant teaches that 1 nm = 1 mμ, not that 1 nm = 1μm as written in Rudin et al. Therefore, the size of the hydroxylapatite particle compares with and falls within the claimed dimensions.

Conclusion

No claim is allowed.

Applicant's amendment to claim 16 wherein the limitation "wherein the rodlet-like primary nanoparticles of the calcium salts are uniformly associated onto the skeleton of the protein component."t necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Graffeo whose telephone number is 571-272-8505. The examiner can normally be reached on 9am to 5:30pm Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

20 August 2005
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